

REMARKS

Upon entry of the foregoing amendments, Claims 8-17 are pending. Because the number of claims remain less than or equal to 20 and the number of independent claims remain less than or equal to 3, no additional claims fees are required. Because all of the pending claims are new, there is no need to append marked-up claims. The new claims do not contain new matter, because they are either based on the prior pending claims, and/or they find support in the specification.

Multiple Depending Claim Objection

The Examiner objected to Claim 6 as a multiple dependent claim depending from another multiple dependent claim. It is apparent that there was some confusion as to the claims that were entered in the National Stage. The Examiner apparently examined Claims 1-7 as issued with the International Preliminary Examination Report. However, upon entry in the National Stage, Applicants submitted Claims 1-10 that were to be entered in place of the IPER claims. It is apparent that the Examiner did not address those claims. Therefore, Applicants will address the claims addressed by the Examiner as Claims 1-7. In any case, this rejection is now moot in light of the cancellation of Claims 1-7 in favor of new Claims 8-17.

35 U.S.C. 112 ¶ 2

The Examiner contends that Claim 5 was indefinite for reciting the term "substantially as herein described in any of the Examples." Once again, this is a consequence of the confusion over the claims entered in the National Stage. Once again, the cancellation of Claim 5 renders this rejection moot.

35 U.S.C. 102 and 103 (Maeda)

The Examiner contends that Claims 1, 2 and 7 are anticipated by or obvious over Maeda (EPO Doc. No. 0 276 561 A1). Although the rejections are moot in light of the cancellation of the claims at issue, Applicants believe that it may be helpful to the Examiner to explain the pending claims in light of Maeda.

Independent Claim 8, and therefore all the remaining claims that depend therefrom, require that the concentration of active substance in solvent to be under saturation. Moreover, the concentration of active substance in solvent remains under saturation even after the solution has been admixed in an adhesive, applied as a film to a substrate such as a release liner or a backing sheet, and dried.

Nothing in Maeda, teaches or suggests such a limitation. In Maeda, the solubilization of the active substance in a solvent is actually an optional step. See page 2, line 37-39 ("comprises ... **preferably** in conjunction with an organic solubilizing agent.") and page 3, lines 25-27 ("In accordance with a **preferred embodiment** of the present invention, the mixture ... **can** thereafter be further dissolved and dispersed in a solubilizing

agent."). Although Maeda indicates that up to 20 parts solubilizing agent may be added per one part active substance, it indicates that a 2 part solubilizing agent to active substance ratio is preferred. For crotamiton this is further supported in Example 2, which shows a 1.0g crotamiton to 0.5g piroxicam ratio.

As preferred or exemplified, such a ratio would provide a saturated or supersaturated solution. Moreover, Maeda does not teach drying the composition at a temperature below the boiling point of the solvent in order to maintain a below saturation concentration of active substance/solvent solution. Therefore, the ordinary artisan would be guided by the belief at that time that supersaturation was necessary for transdermal compositions. Because Maeda teaches neither forming a less than saturated active substance/solvent solution, nor maintaining the less than saturated solution by drying at less than the boiling point of the solvent, it cannot anticipate the pending claims. Moreover, in the absence of a specific teaching or suggestion of forming a less than saturated solution of active substance and solvent, or of maintaining the concentration at less than saturation by drying the composition at less than the boiling temperature of the solvent, Maeda cannot render the pending claims obvious.

35 U.S.C. 103 (Jenkins)

The Examiner rejected Claims 1, 3-4 and 7 as obvious in light of Jenkins (U.S. 5,352,457). Although these rejections are also moot in light of the present amendments cancelling the prior claims, Applicants will point out that Jenkins cannot render the currently pending claims obvious because it teaches formation of

a supersaturated solution of active substance. By contrast, the pending claims form a less than saturated solution of active substance, and maintains the solution at less than saturation. In fact, Jenkins is the U.S. equivalent of G.B. 2249956, distinguished by applicants in the background of the present invention. Because Jenkins does not teach or suggest one or more limitations of the pending claims, it cannot render the pending claims obvious.

35 U.S.C. 103 (Maeda, Jenkins and Hirano)

The Examiner rejected Claims 1-4 and 7 as obvious in light of Maeda, Jenkins and Hirano (U.S. 5,820,878). Although these rejections are now moot in light of the present amendments cancelling the prior claims, and adding new Claims 8-17, Applicants will nevertheless point out why the cited references, alone or in combination cannot render the currently pending claims obvious.

As discussed above, the presently pending Claims 8-17 require the formation of a less than saturated solution of active substance and solvent, and maintaining a less than saturated solution during preparation of the final composition, by drying the preparation at a temperature that is less than the boiling point of the solvent. Maeda and Jenkins were discussed above. Hirano teaches melting base ingredients then adding the active substance and crotamiton. Alternatively, Hirano teaches dissolving all ingredients in an organic solvent (as opposed to the penetration enhancer which serves as a solvent in the present invention), then removing the organic solvent. It is apparent

that nothing in any of the cited references, alone or in combination, teach or suggest a procedure as claimed in the presently pending claims.

Conclusion

For at least the foregoing reasons, Applicants believe that the pending claims are patentable, and respectfully request allowance. If there are any other matters that need to be addressed prior to allowance, please call the undersigned at the telephone number recited below for a telephone disposition. Finally, while Applicants do not believe that any additional fee, aside from any separately authorized petition for extension fee, is required, the Commissioner is hereby authorized to charge any additional fees which may be required in this application to Deposit Account No. 06-0040. In the case of overpayment, please credit the same account.

Faier and Faier, P.C.
566 West Adams Street, #600
Chicago, Illinois 60661
Telephone: 312-382-9500
Facsimile: 312-382-9200

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Respectfully submitted,
Faier and Faier, P.C.

By Frank Z. Yang
Frank Z. Yang (35417)